

ENZYMATIC THERADY INCORPORATED

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INTEGRATIVE THERAPEUTICS INC." NF Formulas + PhytoPharmica Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 + F: 503.582.0467

ENZYMATIC THERAPY PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 + F: 888.570.6460 (Enzymatic) P: 920.469.9099 + F: 920.469.4418 (Phyto)

July 29, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Mega MultiVitamin Drink Mix	Required with iron for synthesis of hemoglobin.*	Copper (as copper gluconate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Michael P. Devereux Chief Financial Officer

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July 29, 2004

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Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Lab

Label Claims/Disclaimers

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Mega MultiVitamin Drink Mix	Component of coenzymes in electron transport chain and enzyme necessary for melanin pigment formation.*	Copper (as copper gluconate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely

Michael P. Devereux Chief Financial Officer



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PHYTOPHARMICA'

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July 30, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Mega MultiVitamin Drink Mix	Supports healthy carbohydrate metabolism; helps maintain healthy blood glucose concentration already within normal range; may increase insulin binding and the number of insulin receptors.*	Chromium (as chromium picolinate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Michael P. Devereux Chief Financial Officer

Mega MultiVitamin Drink Mix 34e



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July 31, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Mega MultiVitamin Drink Mix	A form of amino acid cysteine; enhances the production of the enzyme glutathione, a powerful antioxidant; supports healthy immune functioning; supports healthy liver functioning; supports healthy mucous production; antioxidant activity.*	N-Acetylcysteine (NAC)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Bv:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date

7/21/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely

Michael P. Devereux Chief Financial Officer

Mega MultiVitamin Drink Mıx 48e



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ENZYMATIC THERADY INCORPORATED

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August 1, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

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Dear Sir or Madam:

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Mega MultiVitamin Drink Mix	Lutein is an antioxiant. It scavanges free reactive oxidative species.*	Lutein (from Calendula officinalis)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 8/1/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Michael P. Devereux Chief Financial Officer